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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,472	11/14/2003	Charles A. Vacanti	07917-082003	1928

23579 7590 03/03/2005

PATREA L. PABST
PABST PATENT GROUP LLP
400 COLONY SQUARE
SUITE 1200
ATLANTA, GA 30361

EXAMINER

NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 03/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/713,472

Applicant(s)

VACANTI ET AL.

Examiner

Christopher J Nichols, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 22-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. The Preliminary Amendment filed 14 November 2003 has been received and entered in full.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims **22-40**, drawn to a *tissue support structure*, classified in class 424, subclass 426, for example.
 - II. Claims **41-42**, drawn to an isolated mammalian adult autonomic nervous system *neural stem cell*, classified in class 325, subclass 368, for example.
 - III. Claims **43-44**, drawn to an isolated mammalian adult *neuroendocrine stem cell*, classified in class 325, subclass 369, for example.
3. The inventions are distinct, each from the other because of the following reasons:
4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons.
5. Inventions I, II, and III are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

6. The tissue forming structure of Invention I is independent and distinct from Inventions II and III because it can be used in methods which are materially different from the neural stem cell of Invention II and the neuroendocrine stem cell of Invention III, such in cell-based therapy, a cell-scaffolding model, or drug release structure.

7. Although the neural stem cell of Invention II can be used to make the tissue forming structure of Invention I, it is independent and distinct from Invention I because it can be used in other materially different methods, such as in various biochemical or therapeutic methods. In addition, the neural stem cell of Invention II can be prepared by processes which are materially different from tissue forming structure of Invention I, such as by isolation and purification from natural sources. The neural stem cell of Invention II can be prepared by processes which are materially different from neuroendocrine cell of Invention III, such as by isolation and purification from natural sources.

8. Although the neuroendocrine stem cell of Invention III can be used to make the tissue forming structure of Invention I, it is independent and distinct from Invention I because it can be used in other materially different methods, such as in various biochemical or therapeutic methods. In addition, the neuroendocrine stem cell of Invention III can be prepared by processes which are materially different from tissue forming structure of Invention I, such as by isolation and purification from natural sources. The neuroendocrine stem cell of Invention III can be prepared by processes which are materially different from neural cell of Invention II, such as by isolation and purification from natural sources.

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

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- a. Polysaccharides
- b. Proteins
- c. Polyphosphazenes
- d. Poly(oxyethylene)-poly(oxypropylene) block polymers
- e. Poly(oxyethylene)-poly(oxypropylene) block polymers of ethylene diamine
- f. Poly(acrylic acids)
- g. Poly(methacrylic acids)
- h. Copolymers of acrylic acid and methacrylic acid
- i. Poly(vinyl acetate)
- j. Suflonated polymers

10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim **34** is generic.

11. If applicant selects Invention I, one species from the hydrogel group must be chosen to be fully responsive.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. This application contains claims directed to the following patentably distinct species of the claimed invention:

- k. Epidermal cells
- l. Chondrocytes and other cells that form cartilage
- m. Macrophages
- n. Dermal cells
- o. Muscle cells
- p. Hair follicles
- q. Fibroblasts
- r. Organ cells
- s. Osteoblasts and other cells that form bone
- t. Endothelial cells
- u. Mucosal cells
- v. Pleural cells
- w. Ear canal cells

- x. Tympanic membrane cells
 - y. Peritoneal cells
 - z. Schwann cells
 - aa. Corneal epithelial cells
 - bb. Gingiva cells
 - cc. Neural cells
 - dd. Neural stem cells
 - ee. Tracheal epithelial cells
16. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 35 is generic.
- 17. If applicant selects Invention I, one species from the tissue precursor cell group must be chosen to be fully responsive.**
18. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
19. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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20. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

21. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

22. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Christopher James Nichols, Ph.D.** whose telephone number is **(571) 272-0889**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

CJN

March 1, 2005

A handwritten signature in black ink, appearing to read "C. Nichols", is written in a cursive style.